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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,515	01/02/2004	Nathan Karin	27363	9523

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,515	KARIN ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, and 11-13 drawn to an antibody capable of specifically neutralizing an interferon gamma inducing factor, and an article of manufacture comprising said antibody, classified in class 530, subclass 387.1.

II. Claims 5-7, drawn to methods of inducing protective immunity against a T-cell mediated autoimmune disease by administering cells capable of producing an antibody capable of specifically neutralizing an interferon gamma inducing factor, classified in class 424, subclass 93.21.

III. Claims 8-10, and 36-37, drawn to methods of inducing protective immunity against a T-cell mediated autoimmune disease by administering an antibody capable of specifically neutralizing an interferon gamma inducing factor, classified in class 424, subclass 130.1.

IV. Claims 14-21, drawn to methods of inducing protective immunity against multiple sclerosis comprising administering a nucleic acid construct encoding a polypeptide capable of eliciting antibodies against interferon gamma inducing factor, classified in class, 514, subclass 44.

V. Claims 22-28, drawn to methods of inducing protective immunity against a T cell mediated autoimmune disease comprising administering genetically modified cells which express interferon gamma inducing factor, classified in class 424, 93.21.

VI. Claims 29-35, drawn to an article of manufacture comprising a nucleic acid encoding a polypeptide capable of eliciting antibodies against interferon gamma inducing factor and a pharmaceutical carrier comprising a delivery vehicle which is a cell, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

1) Inventions II-V are directed to related methods for inducing protective immunity against a T cell mediated autoimmune disease. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of inventions II-V require the administration of patentably distinct products which have materially different physical, chemical, structural, and functional properties. Specifically, an antibody, a cell which produces and antibody, a nucleic acid encoding an interferon gamma inducing factor, and a cell genetically modified to express interferon gamma inducing factor are all materially different products that are not obvious variants as evidenced by their substantially different physical and functional properties, and also in view of their different modes of operation and function. As such, the search for each of these inventions is not coextensive with the others, and it would place an undue burden on the examiner to search and examine all of inventions II-V together.

2) Inventions I and Invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the methods can be practiced by other materially different products as evidenced by the claims of inventions II and IV-V, and the antibodies of invention I can be used in methods other than those of invention III, such as the use of the antibodies in in vitro binding assays, or the use of the antibodies as in vivo diagnostic reagents. As such, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine both inventions together.

3) Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the methods can be practiced by other materially different products as evidenced by the claims of inventions II-III and V, and the nucleic acids of invention VI can be used in methods other than those of invention IV, such as the use of the nucleic acids in in vitro binding assays, or the use of the nucleic acids to transfect cells in vitro. As such, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine both inventions together.

4) Inventions I and VI are unrelated. Invention I is drawn to an antibody capable of specifically neutralizing an interferon gamma inducing factor, which is a product that is materially different in structural, chemical, biological, and functional properties than a nucleic acid encoding a polypeptide capable of eliciting an antibody. Further, the products are made

using different reagents and techniques and are used for substantially different purposes. As such, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine both inventions together.

5) Inventions I and inventions II, IV and V are patentably distinct in that the antibodies of invention I are not required or useful in the methods of invention II, IV and V, which utilize products substantially different in properties and functions from the products of invention I. Note in particular that an antibody is materially different from a cell which produces an antibody in structural, chemical, physical, and functional properties, is made using different reagents and techniques, and can be used for substantially different purposes such as the use of the antibodies in detection agents in western blot assays or in FACS analysis. As such, the search for these invention is not co-extensive and it would place an undue burden on the examiner to search and examine all inventions together.

6) Inventions VI and inventions II-II and V are patentably distinct in that the nucleic acids of invention VI are not required or useful in the methods of invention II-III and V, which utilize products substantially different in properties and functions from the products of invention I. Note in particular that a nucleic acid encoding a polypeptide capable of inducing antibodies is materially different from a genetically modified cell which expresses interferon gamma inducing factor in structural, chemical, physical, and functional properties, is made using different reagents and techniques, and can be used for substantially different purposes such as the use of the nucleic acids in *in vitro* binding assays or the use of the nucleic acids to produce a protein *in vitro*. As such, the search for these inventions is not co-extensive and it would place an undue burden on the examiner to search and examine all inventions together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of T cell mediated autoimmune diseases:

a) multiple sclerosis

b) rheumatoid arthritis

c) type I diabetes

d) uveoretinitis

e) Chrohn's disease

f) ulcerative colitis.

The species are independent or distinct because each is a separate disease with unique etiology and symptoms such that the search for one disease is not coextensive with the search for any of the other diseases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic.

This application also contains claims directed to the following patentably distinct species of carriers for invention VI:

g) lipids, artificial or natural

h) oils

i) esters

j) glycol

h) a virus

i) metal particles

j) a delivery vehicle that is a liposome

k) a delivery vehicle that is a cell

l) a delivery vehicle that is a micelle

The species are independent or distinct because each is a separate carrier has distinct chemical, physical, structural, and functional properties such that the search for one is not coextensive with the search for any of the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 29, and 33-36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention and species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER